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[Notices]
[Page 51918-51919]
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ENVIRONMENTAL PROTECTION AGENCY
[FRL-6170-1]

Nominations for Peer Reviewers for Perchlorate Toxicological Review

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Request for nominations.

SUMMARY. EPA's Office of Solid Waste and Emergency Response has retained Research Triangle Institute, Inc. (RTI) to coordinate a scientific peer review of the Toxicological Review document for perchlorate, including the revised provisional reference dose (RfD), cancer assessment and ecological assessment. The peer review workshop is tentatively scheduled to be held in late 1998 or early 1999, in Ontario, California, and will be open to members of the public as observers. The peer review will be conducted in accordance with EPA's 1998 Peer Review Handbook, and is being organized to assist in completing EPA's evaluation of the effects on human health and the environment of perchlorate. RTI is seeking nominations of highly qualified scientists with expertise in general toxicology, thyroid function and toxicology, developmental toxicology, neurotoxicology, immunotoxicology, pharmacology, genetic toxicology, medical endocrinology with an emphasis on thyroid function, biostatistics, assessment of risks due to non-cancer and cancer health effects, and assessment of risks due to ecological effects. RTI will select approximately 10 objective peer reviewers based upon demonstrated expertise of the scientists and the need for balance in affiliation among the peer reviewers. RTI will consider potential conflicts of interest in screening nominees for suitability as peer reviewers. All nominations will be carefully considered, but the source of peer reviewer nominations will not be a factor in the selection of peer reviewers and stakeholders are not guaranteed that any of their nominees will be selected. The peer review will cover the protocols and results of ongoing studies of perchlorate toxicity to human health and the environment, as well as the Toxicological Review document, including the revised provisional RfD, cancer assessment, and ecological assessment for perchlorate prepared by EPA's National Center for Environmental Assessment (NCEA).

DATES: Nominations for peer reviewers must be submitted by October 29, 1998. A detailed resume for each nominated scientist should be included with the submission. The projected date for the peer review workshop is late 1998 or early 1999, depending on the availability of the peer reviewers.

ADDRESSES: Peer reviewer nominations should be sent to Susan Goldhaber at Research Triangle Institute, Inc., P.O. Box 12194, Research Triangle Park, North Carolina, 27709. Peer reviewer nominations may also be submitted by facsimile at 919-541-7155, or by E-mail at sbg@rti.org. The peer review workshop will be held in Ontario, California.

FOR FURTHER INFORMATION CONTACT: For technical and logistical inquiries, contact Susan Goldhaber, Research Triangle Institute, by telephone, at 919-541-5965, by facsimile, at 919-541-7155, or by E-mail, at sbg@rti.org.

SUPPLEMENTARY INFORMATION:

Background

EPA is in the process of developing a toxicological review document for perchlorate, including a revised provisional RfD, cancer assessment, and ecological assessment. An RfD is an estimate of a daily oral human

exposure that will result in no deleterious noncancer effects over a lifetime. Ideally, an RfD is based on an array of endpoints that address potential toxicity during various critical life stages, from developing fetus through adult and reproductive stages. The noncancer, cancer and ecological assessments may be used to support development of a health advisory and/or drinking water regulations and cleanup decisions at hazardous waste sites. In accordance with EPA's 1998 Peer Review Handbook, a key step in the development of the Toxicological Review document for perchlorate will be an external peer review, in the form of a workshop, of the recently completed toxicity studies, the Toxicological Review document, and the revised provisional RfD, cancer assessment and ecological assessment in that document. EPA's Superfund Technical Support Center issued a provisional RfD for perchlorate in 1992 and a revised provisional RfD in 1995. The provisional RfD values (1992 and 1995) were based on an acute study in which

[[Page 51919]]

single doses of potassium perchlorate caused the release of iodide from the thyroids of patients with Graves' Disease. The provisional RfD values did not undergo internal Agency or external peer review. In March of 1997 a peer review panel convened by an independent organization, Toxicology Excellence for Risk Assessment (TERA), determined that the health effects and toxicity data for perchlorate were insufficient to generate a credible RfD for risk assessment purposes. The reviewers were concerned that developmental toxicity, notably neurological development due to hypothyroidism during pregnancy, could be a critical effect of perchlorate that has not been adequately examined in studies to date. They also concluded that insufficient data were available on potential effects of perchlorate on organs and tissues other than the thyroid. New Health Effects/Toxicology Studies Underway A set of toxicological and ecological studies is underway to address key data gaps and provide a comprehensive database related to the toxicity of perchlorate. The studies are being funded and overseen by a variety of organizations with potential responsibility for perchlorate contamination in the environment including the United States Air Force, the National Aeronautics and Space Administration and the Perchlorate Study Group (PSG).¹

\1\ The PSG is a consortium of defense contractors and manufacturers including: Aerojet, Alliant Techsystems, American Pacific/Western Electrochemical Company, Atlantic Research Corporation, Kerr-McGee Chemical Corp. Lockheed Martin, Thiokol Propulsion Group, and United Technologies Chemical Systems.

To date, a 90-day subchronic oral study, a neurobehavioral developmental toxicity study, and a genotoxicity study have been completed. Currently ongoing studies include a segment II developmental toxicity study, a two-generation reproductive toxicity study, absorption, distribution, metabolism, and elimination (ADME) studies, perchlorate mechanistic studies, and immunotoxicity studies. Ecotoxicity studies in Daphnia, earthworms, lettuce and fathead minnow are also being performed. The results of most of these studies will be available for discussion in the Toxicological Review document and for development of the revised RfD, cancer, and ecological assessment for perchlorate.

The peer review will focus on the scientific data, methods, and analyses, along with the assumptions and uncertainties that are associated with the revised provisional RfD, cancer assessment, and ecological assessment for perchlorate. Following the peer review workshop, RTI will issue a report summarizing the workshop. EPA will consider the results of the workshop prior to issuing the revised Toxicological Review document for perchlorate. Although the completed risk assessment will be one of the factors considered in making future decisions regarding perchlorate contamination in the environment, these decisions and other risk management issues will not be a part of the peer review process.

Dated: September 23, 1998.
Timothy Fields, Jr., Acting Assistant Administrator,
Office of Solid Waste and Emergency Response.
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